IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACURA PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
RANBAXY INC. and RANBAXY LABORATORIES LTD.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Acura Pharmaceuticals, Inc. ("Acura") files this Complaint for patent infringement against Ranbaxy Inc. and Ranbaxy Laboratories Ltd. under 35 U.S.C. § 271. This patent action concerns the pharmaceutical drug product Oxecta®. Plaintiff, Acura, hereby states as follows:

JURISDICTION AND PARTIES

1. Plaintiff Acura is a New York corporation that has its corporate offices and principal place of business at 616 N. North Court, Suite 120, Palatine, Illinois 60067. Acura is engaged in the business of research, development, and manufacture of pharmaceutical products in the United States. Acura is the current owner of United States Patent No. 7,510,726 ("the '726 patent").

2. On information and belief, Ranbaxy Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 600 College Road East, Princeton, NJ 08540.

3. On information and belief, Ranbaxy Inc. is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

4. This Court has personal jurisdiction over Ranbaxy Inc. because, on information and belief, it is incorporated in Delaware and purposely avails itself of the privilege of doing business in Delaware.

5. In addition, on information and belief, personal jurisdiction over Ranbaxy Inc. is proper because of its regular marketing and sales activities in Delaware, including the substantial, continuous, and systematic distribution and sales of generic drug products to residents of Delaware. It purposefully avails itself of the privilege of selling generic products in Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware.

6. On information and belief, Ranbaxy Laboratories Ltd. ("Ranbaxy Labs") is a corporation organized and existing under the laws of the Nation of India, having its corporate headquarters at 12th Floor, Devika Tower, 6, Nehru Place, New Delhi 110019, Delhi, India.

7. On information and belief, Ranbaxy Labs is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

8. This Court has personal jurisdiction over Ranbaxy Labs because it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hailed into court here. On information and belief, Ranbaxy Labs has had persistent, systematic, and continuous contacts with Delaware within the meaning of DEL. CODE ANN. Tit. 10 § 3104(c)(4) (West 2012), as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

9. On information and belief, Ranbaxy Inc. is a wholly-owned subsidiary of Ranbaxy Labs, and Ranbaxy Inc. acts as the U.S. agent for Ranbaxy Labs in connection with the sale of pharmaceutical products in the United States, including the State of Delaware.

10. On information and belief, Ranbaxy Labs does business in the State of Delaware and has derived substantial revenue from sales of pharmaceutical products in Delaware.

11. On information and belief, Ranbaxy Labs has previously availed itself of this forum for the purposes of litigating of its patent disputes by, *inter alia*, admitting or submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction: *Merck & Co., Inc. v. Ranbaxy Inc.*, Civil Action No. 1:07-cv-00229-GMS (D. Del. June 21, 2007) and *Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, Civil Action No. 1:07-cv-00138-JJF (D. Del. March 29, 2007).

12. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2). This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '726 Patent Under 35 U.S.C. § 271(e)(2))

13. Acura realleges and incorporates by reference paragraphs 1-12.

14. The '726 patent, entitled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms," was duly and legally issued to Acura by the United States Patent and Trademark Office ("USPTO") on March 31, 2009. The patent claims, *inter alia*, abuse deterrent dosage forms of oxycodone. The '726 patent expires on March 16, 2025. This expiration date results from a terminal disclaimer corresponding to the expiration date of U.S.

Patent No. 7,201,920, granted by the USPTO pursuant to 35 U.S.C. § 253. A true and correct copy of the '726 patent is attached as Exhibit A. A true and correct copy of the terminal disclaimer is attached as Exhibit B. Since its date of issue, Acura has been, and continues to be, the owner of the '726 patent.

15. On June 17, 2011, the FDA approved New Drug Application ("NDA") No. 20-2080 for the use of Oxecta® for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. The Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") lists the '726 patent for NDA No. 20-2080.

16. On information and belief, Ranbaxy Inc. and Ranbaxy Labs (collectively "Ranbaxy") filed or caused to be filed with the FDA ANDA No. 20-4056 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of oxycodone hydrochloride tablets, 5 mg and 7.5 mg ("Ranbaxy's Oxycodone HCl Tablets"), in the United States before the expiration of the '726 patent.

17. On information and belief, ANDA No. 20-4056 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"), alleging that the claims of the '726 patent are either invalid or will not be infringed by Ranbaxy's Oxycodone HCl Tablets.

18. Ranbaxy sent or caused to be sent to Acura a letter ("Ranbaxy's Notice Letter") dated April 2, 2013, notifying Acura that Ranbaxy filed ANDA No. 20-4056 and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Ranbaxy's Notice Letter alleges noninfringement of all the claims of the '726 patent. Although required to provide specific

allegations of invalidity, Ranbaxy failed to do so and instead generically stated that the '726 patent is invalid.

19. Under 35 U.S.C. § 271(e)(2)(A), Ranbaxy's submission of ANDA No. 20-4056 to the FDA to obtain approval for the commercial manufacture, use, or sale of Ranbaxy's Oxycodone HCl Tablets in the United States before the expiration date of the '726 patent constitutes an act of infringement. If ANDA No. 20-4056 is approved by the FDA, Ranbaxy's commercial manufacture, use, sale, or offer to sell in, or importation into the United States of its Oxycodone HCl Tablets would infringe, either literally or under the doctrine of equivalents, one or more claims of the '726 patent under 35 U.S.C. § 271.

20. On information and belief, Ranbaxy has knowledge of the '726 patent and has filed ANDA No. 20-4056 seeking authorization to commercially manufacture, use, offer for sale, and sell Ranbaxy's Oxycodone HCl Tablets in the United States. On information and belief, Ranbaxy knows and intends that physicians, health care providers, and/or patients will use Ranbaxy's Oxycodone HCl Tablets in accordance with the indications sought by Ranbaxy, and Ranbaxy will therefore induce the infringement, either literally or under the doctrine of equivalents, one or more claims of the '726 patent under 35 U.S.C. § 271.

21. Acura will be substantially and irreparably harmed by Ranbaxy's infringing activities unless those activities are enjoined by this Court. Acura has no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '726 Patent Under 35 U.S.C. § 271(a) and/or (b))

22. Acura realleges and incorporates by reference paragraphs 1-21.

23. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a) and (b), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

24. On information and belief, Ranbaxy filed or caused to be filed with the FDA ANDA No. 20-4056 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Ranbaxy's Oxycodone HCl Tablets in the United States before the expiration of the '726 patent.

25. On information and belief, if the FDA approves ANDA No. 20-4056, Ranbaxy and/or its agents plan to begin the commercial manufacturing, marketing, selling, and/or offering to sell Ranbaxy's Oxycodone HCl Tablets in the United States immediately or soon after receiving FDA approval for the indication(s) sought in ANDA No. 20-4056. Such conduct will constitute infringement, either literally or under the doctrine of equivalents, of one or more claims of the '726 patent under 35 U.S.C. §§ 271(a) and/or (b).

26. On information and belief, Ranbaxy has knowledge of the '726 patent and has filed ANDA No. 20-4056 seeking authorization to commercially manufacture, use, offer for sale, and sell Ranbaxy's Oxycodone HCl Tablets in the United States. On information and belief, Ranbaxy knows and intends that physicians, health care providers, and/or patients will use Ranbaxy's Oxycodone HCl Tablets in accordance with the indications sought by Ranbaxy, and Ranbaxy will therefore induce the infringement, either literally or under the doctrine of equivalents, one or more claims of the '726 patent under 35 U.S.C. § 271(b).

27. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Acura and Ranbaxy as to liability for the infringement of the '726 patent. Ranbaxy's actions have created in Acura a reasonable

apprehension of irreparable harm and loss resulting from Ranbaxy's threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Acura respectfully requests that this Court enter judgment in its favor as follows:

a) declare that United States Patent No. 7,510,726 is valid;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Ranbaxy infringed the '726 patent by submitting ANDA No. 20-4056 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Ranbaxy's Oxycodone HCl Tablets prior to the expiration of said patent;

c) declare that Ranbaxy's commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Ranbaxy's Oxycodone HCl Tablets prior to the expiration of the '726 patent would constitute infringement of said patent under 35 U.S.C. § 271(a) and/or (b) as set forth above and in violation of Acura's patent rights;

d) order that the effective date of any FDA approval of Ranbaxy's Oxycodone HCl Tablets shall be no earlier than the expiration date of the '726 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Ranbaxy, and all persons acting in concert with Ranbaxy, from seeking, obtaining, or maintaining approval of ANDA No. 20-4056 until the expiration of the '726 patent;

f) enjoin Ranbaxy, and all persons acting in concert with Ranbaxy, from commercially manufacturing, using, offering for sale, or selling Ranbaxy's Oxycodone HCl Tablets within the United States, or importing Ranbaxy's Oxycodone HCl Tablets into the

United States, until the expiration of the '726 patent, in accordance with 35 U.S.C. § 271(e)(4)(B); and

g) grant Acura such further and additional relief that this Court deems just and proper.

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